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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
| 10/083,707 | 02/26/2002 | Gregory G. Brucker | 15305.32USU1 | 1518 |
| 23552 | 7590 | 07/15/2008 | EXAMINER | |
| MERCHANT & GOULD PC | | | TYSON, MELANIE RUANO | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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|------------------------------|--------------------------------------|---------------------------------------|
| Office Action Summary | Application No. 10/083,707 | Applicant(s) BRUCKER ET AL. |
| | Examiner Melanie Tyson | Art Unit 3773 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED. (35 U.S.C. § 133).

Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 23 April 2008.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 17,19 and 39-62 is/are pending in the application.
 - 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 17,19, and 32-62 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO/146/08)
 Paper No(s)/Mail Date _____
- 4) Interview Summary (PTO-413)
 Paper No(s)/Mail Date _____
- 5) Notice of Informal Patent Application
- 6) Other: _____

DETAILED ACTION

This action is in response to applicant's amendment received on 23 April 2008.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 47-56 and 62 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. At the time the application was filed, the applicant failed to disclose that after expansion of the bulge portion, "a portion of the bulge portion is positioned within the circumferential plane." Therefore, this limitation is considered new matter.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. Claims 17, 19, 39, 40, 46, 57, 58 and 61 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lam (5,607,444) in view of Vardi et al. (6,325,826).

Lam discloses a system (see entire document) comprising only a single catheter having only a single balloon (for example, see Figures 1 and 6), and a bifurcation stent (for example, see Figures 2 and 3) including a stent body (20) and a plurality of movable members (25) engaged to the stent wall, retained substantially within the plane of the stent wall, and expandable radially outward from the stent wall to form a scaffold. Lam further discloses the movable members and stent body may be balloon expandable or self-expandable, and the bifurcation stent may be a hybrid stent such that a portion may be self-expandable while the other portion is balloon expandable, wherein both portions may be expanded simultaneously (for example, see column 7, line 20 - column 8, line 16). Lam fails to disclose the scaffold defines a side opening in the stent wall.

Vardi discloses a system (see entire document) comprising a bifurcation stent including a stent body and a plurality of movable members that extends radially outward from the stent wall to form a scaffold (for example, see Figure 8). Vardi teaches the scaffold defines a side opening in the stent wall, such that a portion of the movable members expand towards a proximal end of the stent body and a portion of the movable members expand towards a distal end of the stent body (for example, see Figure 8). It is well within the general knowledge of one having ordinary skill in the art to apply a known

technique to a known device to yield predictable results. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the movable members on a side wall, such that they radially expand from a scaffold defining a side opening in the stent wall as taught by Vardi. Doing so would provide the stent the ability to be positioned across the bifurcation with the side opening positioned over the bifurcation point.

6. Claims 41-45, 59, and 60 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lam (5,607,444) in view of Vardi et al. (6,325,826), and further in view of Crocker et al. (5,843,116).

Lam in view of Vardi discloses a device as described above (see above for similar elements of claims 47-56 and 62), and further discloses a bulge region protruding radially outward from the body region when expanded to aid in expanding the movable members, the bulge region being positioned at a location between a proximal and distal end of the body, wherein in the unexpanded state the movable members are positioned over the bulge (for example, see Figures 1 and 6). However, Lam in view of Vardi fails to disclose the bulge is positioned at a predetermined circumferential location. Lam in view of Vardi discloses expansion and deformation of the stent can be accomplished through the use of various sized and shaped balloons (for example, see column 7, lines 20-23).

Crocker discloses a system (see entire document) comprising a catheter having a balloon (for example, see Figures 1-3). Crocker teaches a bulge region (30) being located between a proximal end and a distal end, wherein the bulge is positioned at a

predetermined circumferential location (for example, see column 1, lines 10-15). Crocker further teaches the expansion characteristics can be achieved by modifying the expansion properties of the balloon itself, including providing zones of differing wall thickness (for example, see column 5, lines 40-45). It is well within the general knowledge of one having ordinary skill in the art to apply a known technique to a known device to yield predictable results. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the balloon of Lam in view of Vardi as taught by Crocker. Doing so would provide higher expansive energy only where needed, such as along the center where the movable members lie across the bifurcation point, thus minimizing the risk of damaging surrounding tissue. With further respect to claims 59 and 62, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the bulge portion such that it extends around less than an entire circumference, since such a change would simply involve changing the shape of the bulge portion (for example, by varying the thickness of the balloon to accomplish a certain shape), and changing shapes and merely involves routine skill in the art (for example, see Bramfit's patent 5,935,135; discloses bulge portions 28b or 28d in Figures 7B and 7D, which extend around less than an entire circumference of the body portion).

7. Claims 47-56 and 62 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vardi et al. (6,325,826 B1) in view of Marotta et al. (6,261,305 B1). Vardi discloses all the limitations of the claims except for a bulge region as claimed. Marotta discloses a catheter system (see entire document) comprising a catheter having a balloon

arrangement. Marotta teaches a bulge portion positioned within the circumferential plane of the body region of the endoprosthesis prior to expansion (for example, see Figure 1) that extends radially through a side opening of the endoprosthesis outside the circumferential plane after expansion (for example, see Figure 4) in order to push a movable member radially outward. It is well within the general knowledge of one having ordinary skill in the art to apply a known technique to use a known technique to improve similar devices in the same way. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Vardi's balloon to have a bulge region to push the movable members outward as taught by Marotta. Doing so would eliminate the step of repositioning the balloon or having to use a second balloon, thus facilitating the deployment and proper placement of the stent.

Response to Arguments

8. Applicant's arguments with respect to claims 47-56 and 62 have been considered but are moot in view of the new ground(s) of rejection.
9. Applicant's arguments filed 23 April 2008 have been fully considered but they are not persuasive. Applicant argues primarily that the prior art applied teaches away from the limitations of claims 17, 57, and 61. Examiner respectfully disagrees.

Applicant argues that since Lam discloses that the movable members are expandable through heat activation, Lam fails to disclose the movable members move into a radially outward extending orientation relative to the stent wall **upon expansion of the balloon expandable portions of the stent**, thus teaches away from the claimed invention. It is the examiner's position that this limitation is not recited in claims 17 and

57. The claim language simply requires that the movable members are extended radially outward from the stent wall in the expanded condition which Lam discloses. With respect to claim 61, Lam teaches the stent wall and movable members may be expandable by expansion of a balloon (for example, see column 7, lines 20-29).

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melanie Tyson whose telephone number is (571)272-9062. The examiner can normally be reached on Monday through Thursday 8:30-7 (max flex).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571) 272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Melanie Tyson /M. T./
Examiner, Art Unit 3773
July 11, 2008

/(Jackie) Tan-Uyen T. Ho/
Supervisory Patent Examiner, Art Unit 3773